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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,225	09/03/2004	Katsutoshi Yoshizato	2004-0990A	7468

513 7590 12/22/2006
WENDEROTH, LIND & PONACK, L.L.P.
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WASHINGTON, DC 20006-1021

EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/500,225

Applicant(s)

YOSHIZATO ET AL.

Examiner

Leon Y. Lum

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 28, 2006 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Medina et al (Biotechnology Techniques, 1997) (hereinafter "Medina").

Medina teaches the step of immobilizing *E. coli* O157:H7 cells on the surface of a BIAcore sensor chip (i.e. immobilizing living cells on a surface surface plasmon

resonance analyzer) and performing binding interactions of the cells with anti-*E. coli* IgG by injecting the IgG at a flowrate for a specific amount of time over the sensor surface (i.e. applying a flow of the specific binding substance) and measuring a continuous, real-time response (i.e. biological activity) before, during (i.e. primary signal), and after (i.e. secondary signal) the injection period. See page 173, right column, 2nd paragraph to page 174, left column, 1st paragraph; and Figure 2 and caption.

Response to Arguments

4. Applicants' arguments filed on September 28, 2006 have been fully considered but are not persuasive.

On pages 3-4 of the response filed on the said date, Applicants state that amendments have been made pursuant to "the Office's suggestion/characterization of the invention on page 4, lines 4-11 of the Action." It is noted that the amended claims now require "a flow of the specific binding substance" instead of an "external stimulus" and "biological activity" instead of "physiological activity."

The cited portion of the previous Office Action pointed out by Applicants is actually a statement on the broadness of the claim. Applicants were notified in the previous Office Action that the formerly claimed "external stimulus" did not constitute physical removal of a specific binding substance, as Applicants had argued in the Response (filed on November 22, 2005) to the first Office Action, because the specification does not provide support for this step. The specification merely mentions

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the initiation and cessation of injections of fluid into devices for determining specific binding reactions. The Examiner therefore considered the term "external stimulus" as broadly construed to include injections of fluid. Since Medina teaches such a stimulus with the requisite measurements before, during, and after the injections, the Examiner indicated that Medina sufficiently taught the claim.

The currently amended claims do not constitute a scope different than the previous claims. Although the terminology has changed, the new terms and phrases do not overcome Medina's teachings. Medina specifically teaches injecting IgG at a flowrate for a specific amount of time over the sensor surface and measuring a continuous, real-time response before, during, and after the injection period. The injection of IgG anticipates the claimed "flow of specific binding substance" and the measurements during and after the injections anticipate the claimed "primary signal" and "secondary signal," respectively. While "biological activity" is now claimed instead of "physiological activity," Medina's teaching of measuring specific binding reactions between IgG and anti-*E. coli* IgG is necessarily a teaching of biological activity.

Applicants' arguments are therefore not found to be persuasive and the rejection made in the previous Office Action is maintained.

Conclusion

5. No claims are allowed.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon Y. Lum
Patent Examiner
Art Unit 1641


LONG V. LE 12/18/06
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